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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
PAUL F. LAESEKE, KELLY ROSE STEVENS, THOMAS C. WINTER, FRED T. LEE, JR., FRANK J. FRONCZAK, JOHN G. WEBSTER, and CONNIE L. DAVIS

Appeal 2008-3002
Application 10/021,622
Technology Center 3700

Decided: August 12, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 5-8 and 10. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a biopsy apparatus that can also cauterize the biopsy area. Claims 5 and 10 are representative of the claims on appeal, and read as follows:

5. A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface;

wherein the electrically conductive surface is a conductive stylet having a first end supported by the introducer shaft.

10. A biopsy needle assembly comprising:

an introducer shaft having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue and communicating by means of an insulated conductor to the second end to connect with a radio frequency cauterizing electrical source;

a large area electrode adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient; and

a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a

tissue sample before cauterization of the insertion path using the electrically conductive surface;

further including a temperature sensor positioned at the electrically conductive surface.

The Examiner relies on the following references:

Roberts	US 6,261,242B1	Jul. 17, 2001
Lennox	US 5,122,137	Jun. 16, 1992

We affirm-in-part.

ISSUE (Anticipation)

The Examiner contends that claim 5 is anticipated by Roberts.

Appellants contend that Roberts fails to teach any element equivalent to a stylet.

Thus, the issue on appeal is: Does Roberts teach a biopsy needle assembly that includes a stylet as required by claim 5?

FINDINGS OF FACT (FF)

FF1. Claim 5 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Roberts.

FF2. The Examiner relies on Roberts for teaching a biopsy sampler which cauterizes the biopsy site after the biopsy is taken (Ans. 3; Roberts Figures 4a-4c).

FF3. According to the Examiner, the sampler includes "an introducer shaft (50) that is a hollow tube that is sized for insertion into the patient along an insertion path to locate a first end of the tube at the biopsy site," wherein a "biopsy needle (14) (see Column 6, lines 51-52) including a sampling means

(30) is fit in the introducer shaft to be guided thereby." (Ans. 3.) Roberts is also cited for teaching that the first end of the introducer shaft includes an electrically conductive surface (22) on a conductive stylet (12) "having a first end supported by the shaft that is adapted to be exposed to tissue and communicates by means of an insulated conductor (28) (see Column 4, lines 46-48) with a radio frequency cauterizing electrical source (see Column 4, lines 40-41)." (Ans. 3, 6.) Roberts is further cited for teaching that a "large area electrode is adapted to contact the patient without production of cauterization temperatures to complete a circuit when a monopolar electrode is used (see Column 6, lines 38-46)."

FF4. As to a "stylet," the Specification teaches that "a guide may be employed for the biopsy needle comprising a sharp rod (stylet) that is housed inside a hollow cylindrical tube (introducer needle)." (Spec. ¶ 0006.)

FF5. Figure 4a of Roberts, as relied upon by the Examiner, is reproduced below:

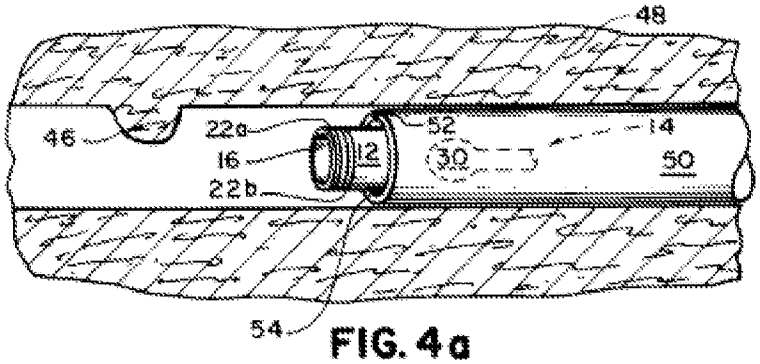

FIG. 4a

Figure 4a shows a side view of the distal portion of the biopsy assembly of Roberts disposed within an endoscope (Roberts, col. 4, ll. 17-19). Reference numeral 12 is a sheath (*see, e.g.*, Roberts col. 6, l. 60), but cannot be said to be a sharp rod.

PRINCIPLES OF LAW

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim. *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001).

Moreover, during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

ANALYSIS

The Examiner, quoting the Merriam-Webster online dictionary, defines stylet as "a 'slender medical probe' or 'a thin wire inserted into a catheter to maintain rigidity or into a hollow needle to maintain patency.'" (Ans. 6.) While claims are given their broadest reasonable interpretation during prosecution before the office, that interpretation has to be consistent with how the ordinary artisan would interpret the term in view of the Specification. In the case before us, the Specification clearly equates the stylet with a sharp rod (FF4), and reference numeral 12 of Figure 4a of Roberts cannot be said to be a sharp rod (FF5). Thus, the Examiner has not established that Roberts teaches every element of claim 5.

CONCLUSION

Thus, we find that the Examiner has not set forth a prima facie case that claim 5 is anticipated by Roberts, and the rejection is reversed.

ISSUE (Obviousness)

The Examiner contends that claims 5-8 and 10 are rendered obvious by the combination of Roberts and Lennox.

Appellants contend that the combination of Roberts and Lennox does not teach all of the elements of the rejected claims.

Thus, the issue on appeal is: Has the Examiner set forth a prima facie case that claims 5-8 and 10 are rendered obvious by the combination of Roberts and Lennox?

FINDINGS OF FACT

FF6. Claims 5-8 and 10 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Roberts and Lennox.

FF7. Claims 6-8 are dependent on claim 5. Claim 10 is a second independent claim that does not require the stylet of claim 5.

FF8. Roberts is relied upon for the teachings set forth above with respect to the anticipation rejection (*see* FF2 and FF3).

FF9. The Examiner finds that Roberts does not teach including a temperature sensor (29, 36) positioned at the electrically conductive surface (28, 35) (Ans. 5).

FF10. Lennox is cited for teaching disposing a temperature sensor at the electrically conductive surface "in order to provide an indirect means of

measuring and controlling the temperature of the tissue surrounding the electrode, so as to prevent excessive tissue damage." (Ans. 5.)

FF11. Figure 1 of Roberts is shown below.

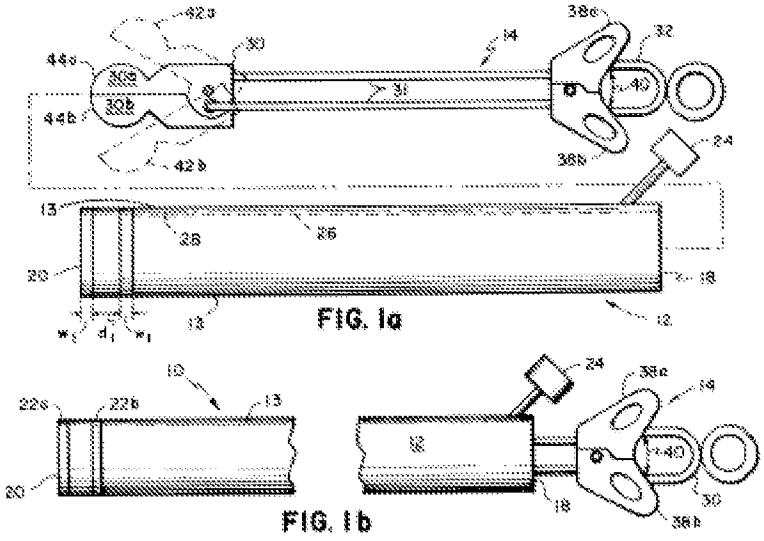

Figure 1 shows a biopsy assembly including a resecting device and a cauterizing sheath (col. 4, ll. 5-6).

FF12. The biopsy assembly 10 includes a cauterizing sheath 12, wherein a pair of bipolar electrodes 22a, 22b, are mounted on the outer sheath surface 13 near distal end 20 (Roberts col. 4, ll. 33-44). The sheath 12 also has an electrical connector 24 for connection to an radio frequency (RF) generator, and two wires 28 are disposed within the lumen 26 connecting the electrodes 22a and 22b to the electrical connector 24 (*id.* at ll. 30-46). The wires are covered with a layer of electrical insulation to prevent electrical contact between the two of them (*id.* at ll. 47-48). RF energy may be applied to the electrodes 22a and 22b through wires 28 and electrical connector 24, causing

current to pass through the resecting site tissue between 22a and 22b (*id.* at col. 6, ll. 14-17). The current heats the resecting site to about 60-100°C, which is sufficient to coagulate the resecting site tissue (*id.* at ll. 17-19).

FF13. Moreover, the sheath need not actually be used for percutaneous insertion, but only need be "sized for percutaneous insertion into a patient." (Claims 5 and 10.) Roberts teaches that the outer diameter of the sheath may be 2.6 mm (Roberts, col. 5, ll. 41-42), and Appellants have not provided any evidence that 2.6 mm is too large to be used for percutaneous insertion.

FF14. Thus, Roberts teaches:

> an introducer shaft [sheath 12] having a first and second end, and sized for percutaneous insertion into a patient along an insertion path to locate the first end at a biopsy site, the first end having an electrically conductive surface adapted to be exposed to tissue [distal end 20 of shaft 10] and communicating by means of an insulated conductor [wires 28] to the second end to connect with a radio frequency cauterizing electrical source; [and]
>
> a large area electrode [electrodes 22a and 22b] adapted to contact the patient without production of cauterizing temperatures to complete a circuit through the radio frequency cauterizing electrical source with the electrically conductive surface of the introducer shaft through a patient.

(Claims 5 and 10.)

FF15. Roberts further teaches that the working lumen 16 of sheath 12 of biopsy assembly 10 is sized to receive a resecting device 14 (Roberts, col. 4, ll. 35-37). The resecting device 14 includes a cutter such as forceps (30) (Roberts, col. 4, ll. 49-51), and may also contain a needle (not shown) to assist in resecting tissue samples (*id.* at col. 6, ll. 51-52). The cutter device 14 is withdrawn within working lumen 16 before the site is cauterized by the

electrodes, preventing the heat at the resecting site from coagulating the tissue specimen (*id.* at col. 6, ll. 8-28).

FF16. We thus find that Roberts also teaches "a biopsy needle interfitting with the introducer shaft to be guided thereby, the biopsy needle including a sampling means for removal of a tissue sample before cauterization of the insertion path using the electrically conductive surface" (Claims 5 and 10).

FF17. Lennox teaches the use of a temperature sensor positioned at an electrically conductive surface (Lennox Abstract). The sensor thus "detects and, by feedback, controls the temperature of the electrode, as an indirect means of measuring and controlling the temperature of tissue contacting the electrode." (*Id.* at col. 2, ll. 39-42.) The feedback process ensures that the tissue is not overheated, allowing the heating process to be predictable and uniform (*id.* at col. 8, ll. 17-26).

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). "The combination of

familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 1739. Moreover, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

ANALYSIS

As to claim 5-8, as Lennox does not remedy the deficiencies of Roberts as to the stylet, we conclude that the Examiner has not set forth a prima facie case of obviousness as to those claims, and we therefore reverse the rejection as to those claims.

Claim 10, however, stands on a different footing. Claim 10 does not require a stylet (FF7). Roberts teaches all of the limitations of claim 10 (FF14 and FF16) except for the temperature sensor (FF9). Lennox teaches the use of a temperature sensor positioned at an electrically conductive surface that allows for predictable and uniform heating of the tissue surrounding the electrode (FF17). Thus, it would have been obvious to position a temperature sensor positioned at the electrically conductive surface of the biopsy assembly of Roberts in order to obtain predictable and uniform heating of the resected tissue. We therefore conclude that claim 10 is rendered obvious by the combination of Roberts and Lennox, and thus turn to Appellants' arguments in rebuttal.

Appellants argue that Roberts, "by inserting the biopsy assembly into the colon and through an endoscope, further teaches away from the need for an element to pierce the skin and the creation of an insertion path that would

require cauterization." (App. Br. 11.) Thus, Appellants assert, "it is not necessary, and indeed not desirable, to include an element to pierce the skin for insertion, and the only cauterization required, and discussed is cauterization of the biopsy site." (*Id.*).

Appellants' arguments are drawn to the intended use of the biopsy assembly, and not the biopsy assembly itself, which is the subject of claim 10. For example, the argument regarding cauterization of the insertion path is an argument as to intended use, and not the structure of claim 10. Moreover, as to the argument as to the inclusion of an element to pierce the skin for insertion, there is nothing in claim 10 that requires an element to pierce the skin.

CONCLUSIONS OF LAW

As Lennox does not remedy the deficiencies of Roberts as to claim 5, we conclude that the Examiner has not set forth a prima facie case of obviousness as to claim 5, nor the claims dependent thereon, *i.e.*, claims 6-8, and thus reverse the obviousness rejection as to claims 5-8.

We do conclude, however, that the combination of references relied upon by the Examiner renders obvious the biopsy assembly of claim 10, and we therefore affirm the rejection as to that claim.

TIME LIMITS

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED-IN-PART

cdc

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